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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,649	06/04/2002	Pierre Belhumeur	1051-1-019	6750

7590 08/02/2006

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EXAMINER	
KIM, TAEYOON	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,649	BELHUMEUR ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2 and 6-13* is/are rejected.

7)☒ Claim(s) *3-5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending.

Election/Restrictions

1. Applicant's election of species in the reply filed on May 22, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Elected species are:

i) Prion protein degradation indicator: (a) Sup35p;

ii) Determination methods: (i) immuno-enzymatic method;

iii) Sterilization processes: (y) sterilization techniques using oxidizing sterilizing agents;

iv) Chemical exposure reagents: no election made

v) Container materials: (f') glass

The Examiner noted that there has been an error in grouping species from Claim 9. Therefore, the species of the claim are now divided into different groups; sterilization process utilizing temperature (autoclaving and dry heating) and sterilization process utilizing chemicals (chemical exposure, low temperature plasma gas, ozone-based exposure, alkyl-group containing chemicals, oxidizing agents). The Examiner has examined the second group of "sterilization process utilizing chemicals" for claim 9. Furthermore, all species listed in claim 10 have been examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being

Claim 9 contains that the term "alkylant" is not known in the art and the specification does not clearly point out what the subject matter it claims. For the purpose of search, this term is interpreted as an "alkyl-group containing chemical."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fungal prion protein degradation indicator selected from the group consisting of sup35, Ure2p and Het-s protein, does not reasonably provide enablement for any other fungal prion-like proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the

state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

In claims 2 and 6, it is claimed that the prion protein degradation indicator of claim 1 is transcribed by a gene naturally occurring in a fungus (claim 2), or a purified form naturally occurring in a fungus (claim 6). Although sup35p, ure2p and Het-s protein, which possess similar biochemical properties such as insolubility in detergent and tendency to form abnormal amyloid filament as the original prion protein (PrP^{Sc}) from scrapie, are recognized as prion proteins (Prusiner, PNAS 1998), the definition for prion proteins are not clearly defined in the art. If the guidance given by the application is used, proteins having detergent insolubility and ability to form amyloids can be used as a prion protein degradation indicator. Aβ protein is one of examples having those biochemical properties. However, although Aβ protein deposited in Alzheimer's disease which is insoluble in detergent and forming amyloid plaques similar to prion protein, Aβ is not considered as a prion protein (Parkin et al. Biochem. J. 1999; DeArmond, Curr. Opin. Neurol. 1993, Abstract). Therefore, there is no clear guidance in the art how to define proteins as prion proteins except those excepted by a person of ordinary skill in the art. This makes the identification of new prion proteins in fungi unpredictable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Reichl (U.S. Patent 5,633,349; issued on May 27, 1997).

Claim 1 is directed to a method of evaluating the efficacy of a sterilization process using the steps of a) subjecting one or more prion protein degradation indicator a container to the sterilization process and b) determining the level of degradation of the indicator.

Claims 6, 7, 9 and 10 are directed to a limitation of the indicator in claim 1 being a recombinant form, an analog of the indicator (claim 6); being biochemical indicator (claim 7); the sterilization process being sterilization techniques using alkyl-containing chemicals and/or oxidizing sterilizing agents (claim 9) or chemical exposure using a detergent (claim 10).

Reichl teaches a method to determine inactivation/elimination of prions comprising steps a) adding scrapie prions into the blood plasma (bovine albumin solution) followed by a sterilization process, and b) determine pathological symptoms of disease or death of animals when inoculated with scrapie prions containing bovine albumin solution as a biochemical indicator (see specific examples: columns 4 and 5).

Reichl teaches the use of chemical exposure as a sterilization process with alkyl sulfate or its derivatives as a detergent or ethylene oxide (claims 9 and 10) in the process of inactivating scrapie prion proteins (column 3, lines 48-50).

Although Reichl does not specifically teach a container for the process of inactivation/elimination of scrapie prions, by practicing the methods of the reference, which involves scrapie prion containing blood plasma, one in the art would inherently be using a container as the claimed method in order to hold the fluid.

Therefore, the reference anticipates the claimed subject matter.

5. Claims 1 and 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Safar et al. (Protein Science, 1993, 2:2206-2216).

Claim 1 is directed to a method of evaluating the efficacy of a sterilization process using the steps of a) subjecting one or more prion protein degradation indicator a container to the sterilization process and b) determining the level of degradation of the indicator.

Claims 6-12 are directed to a limitation of the indicator being an analog or a fragment (claim 6); a biochemical indicator (claim 7); the step of determining the level of degradation of the indicator being performed by immuno-enzymatic method (claim 8); the sterilization process being sterilization techniques using alkyl-containing chemicals and/or oxidizing sterilizing agents or chemical exposure using a detergent (claims 9 and 10); the amount of indicator being between 0.1 ng to 100 g (claim 11); the container being of a glass material (claim 12).

Safar et al. teach a detection of inactivation scrapie prion protein (PrP27-30), which is an analog as well as a fragment of a prion protein (biochemical indicator: claims 6 and 7) in a petri dish (glass: claim 12) after treatment with proteinase K (protease/enzyme; chemical exposure: claims 9 and 10, see Results) or SDS (alkyl-group containing detergent; claims 9 and 10; see Fig.1) for inactivation (see Materials and Methods). Safar also et al. teach the detection was performed by Western blotting analysis (immuno-enzymatic method; claim 8: see Fig. 1).

Although Safar et al. do not particularly teach the amount of indicator being 0.1 ng to 100 g, the reference teaches the amount of scrapie prions in molarity. Safar et al. teach that the amount of prion protein (PrP27-30) used in the method is 0.9 nmol in total 150 µl of water, and the mean molecular weight of each residue is 109.5 (see page 2214; CD spectroscopy). Moreover, it is well known in the art and an inherent property of PrP27-30 to have about 142 amino acid residues supported by Prusiner (PNAS 1998, 95:13368-13383; see Fig. 2). Thus, a person of ordinary skill in the art can calculate the amount of PrP27-30 used in the experiment, and it is about 140 µg (claim 11).

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Safar et al. (supra) in view of Feldman et al. (Compatibility of medical devices and materials with low-temperature hydrogen peroxide gas plasma, 1997; http://www.epotek.com/SSCDocs/whitepapers/Tech%20Paper%2059.pdf).

Claim 9 is directed to limitations to sterilization process of claim 1 being performed by sterilization techniques using low temperature gas plasma or oxidizing sterilizing agents.

Safar et al. teach a method of evaluating the efficacy of a sterilization process using the steps of a) subjecting one or more prion protein degradation indicator a container to the sterilization process and b) determining the level of degradation of the indicator (claim 1)

Safar et al. do not teach the use of low temperature gas plasma or oxidizing sterilizing agents for inactivation/sterilization process.

Feldman et al. teach the use of sterilization process to inactivate prion using oxidizing agents such as hydrogen peroxide as a form of low-temperature gas plasma (column 30, line 33 through column 34, line 42).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the inactivation/sterilization process in the method of Safar et al. with a sterilization technique of Feldman et al. using oxidizing sterilizing agents.

The skilled artisan would have been motivated to make such a modification because conventional sterilization techniques taught by Safar et al. have disadvantage

such that high temperature may cause damage and safety concerns and steam also can corrode metal materials. However, the sterilization technique of Feldman et al. is safer and has no detrimental effects on containers made of various materials.

The person of ordinary skill in the art would have had a reasonable expectation of success in replacing sterilization technique of Safar et al. with that of Feldman et al. because such sterilization techniques of Feldman et al. is commercially available at the time of the invention made. For example, Sterrad system (Advanced Sterilization Products) using a sterilization technique of Feldman et al. which is commercially available.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

7. Claims 9, 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safar et al. (supra) in view of Dresdner Jr. et al. (U.S. Patent 5,357,636).

Claim 9 is directed to a limitation to sterilization process of claim 1 being performed by sterilization techniques using ozone-based exposure.

Claim 10 is directed to a limitation to chemical exposure of claim 9 using sodium hydroxide.

Claim 13 is directed to a limitation to a container of claims 1 and 11 being porous, permeable or semi-permeable.

Safar et al. teach a method of evaluating the efficacy of a sterilization process using the steps of a) subjecting one or more prion protein degradation indicator a

container to the sterilization process and b) determining the level of degradation of the indicator (claim 1)

Safar et al. do not teach ozone-based exposure (claim 9) or sodium hydroxide as chemical exposure (claim 10).

Dresdner Jr. et al. teach the use of ozone (column 22, lines 44-52) or sodium hydroxide (column 27, line 48) as antiseptic composition.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use antiseptic compositions of Dresdner Jr. in the method of Safar et al. to test the efficacy of these sterilization techniques in elimination of prion proteins.

The skilled artisan would have been motivated to make such a modification because various different sterilization techniques are needed to identify the most effective method of prion protein sterilization.

The person of ordinary skill in the art would have had a reasonable expectation of success in use of such antiseptic compositions in the method of prion protein degradation because these antiseptic compositions are well-known as sterilization techniques.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Safar et al. teach a method of evaluating the efficacy of a sterilization process using the steps of a) subjecting one or more prion protein degradation indicator a container to the sterilization process and b) determining the level of degradation of the

indicator (claim 1), and the limitation to the amount of indicator being between 0.1 ng to 100 g (claim 11).

Safar et al. do not teach the container being porous, permeable or semi-permeable (claim 13).

Dresdner Jr. et al. teach a porous and liquid-permeable medical glove for sterilization process (column 18, line 40; column 23, line 56).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace a glass container of Safar et al. with a medical glove of Dresdner Jr. et al.

The skilled artisan would have been motivated to make such a modification because contamination of prion proteins can happen in various different materials such as plastics, metal, or polymer, sterilization process should be carried out in various materials. Moreover, medical gloves are routinely used in hospitals and laboratories and are subject to prion contamination. Therefore, medical gloves of Dresdner Jr. et al. can be used in place of a glass container of Safar et al. to determine effectiveness of various prion sterilization techniques without damaging the material containing a prion protein.

The person of ordinary skill in the art would have had a reasonable expectation of success in replacing a glass container of Safar et al. with a medical glove of Dresdner Jr. et al. because medical gloves used in hospitals and laboratories are subject to routine sterilization to decontaminate pathogens such as prion.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

Claims 3-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 2 and 6-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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